C!PE
MAR 0 9 2001
JC19
PATENT & TRADEMARK OFFICE

REMARKS

Claims 1-75 are pending. Reconsideration of the application is respectfully requested.

I. Rejections Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected the pending claims on the grounds of non-enablement, stating that "the specification, while enabling for a controlled release oral solid dosage form comprising a core of an alkyl ester of a hydroxy substituted naphthalene compound, a pharmaceutically water swellable polymer and an osmotic agent and an outer coating layer which completely covers the core comprising a pH sensitive coating agent and a water insoluble polymer used at a weight ratio of about 0.1:1 to 0.75:1 at a combined coating weight of 0.5-5% by weight, does not reasonably provide enablement for a controlled release oral solid dosage formulation without the recited limitations regarding a core and an outer coating having the weight ratio and combined coating weight."

This rejection is respectfully traversed as Applicants submit that the present invention is enabling for formulations without the above limitations, which have the recited pharmacokinetic parameters. Throughout the present application, various controlled release technologies are discussed which can provide a mean time to maximum concentration (T_{max}) of an alkyl ester of a hydroxy substituted naphthalene which occurs at about 10 to about 32 hours after administration. For example, the dosage form of the invention can be (a) in multiparticulate form, such as inert beads coated with the drug and then overcoated with a controlled release carrier (see page 20); (b) a matrix, wherein a hydrophilic and/or hydrophobic material is included in the matrix with the drug (see page 22); or (c) spheroids comprising the drug, a spheronizing agent and a binder (see page 23).

To further support this position, the Examiner is directed to page 19, line 36 of the application which discloses the following:

***Other controlled release technologies known to those skilled in the art can be used in order to achieve the controlled release formulations of the present invention**, i.e., formulations which provide a mean Tmax of the drug (i.e., a HMG-CoA reductase inhibitor) at the desired time after oral administration, e.g., in general, at about 10 to about 32 hours after oral administration to a population of human patients, and which preferably provide other pharmacokinetic parameters described herein when orally administered to human patients. **Such formulations can be manufactured as a controlled oral formulation in a suitable tablet or multiparticulate formulation known to those skilled in the art.** In either case, the controlled release dosage form may optionally include a controlled release carrier which is incorporated into a matrix along with the drug (e.g., HMG-COA reductase inhibitors), or which is applied as a controlled release coating.*

(Emphasis added)

It is submitted that with the combination of the disclosure provided by the present application (namely, the invention of a dosage form which provides a mean (T_{max}) of an alkyl ester of a hydroxy substituted naphthalene which occurs at about 10 to about 32 hours after administration) with known controlled release technology, one skilled in the art would be enabled to practice the claimed invention.

II. <u>Double Patenting Rejections</u>

In the Office Action, the Examiner rejected the pending claims under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,916,595, which issued from the parent application. The Examiner states that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the claims use open language which allows for the additional components recited."

The Examiner stated that a timely filed Terminal Disclaimer may be used to overcome the rejection.

In response, in order to expedite the issuance of a patent, a Terminal Disclaimer is submitted herewith. Applicants note that the obviation of an obvious-type double patenting rejection by the filing of a terminal disclaimer is not an admission, acquiescence, or estoppel on the merits of an issue of obviousness. *See Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 873-74, 20 U.S.P.Q.2d 1392, 1394-95 (Fed. Cir. 1991).

IV. Conclusion

It is now believed that the above-referenced rejections have been obviated and withdrawal is respectfully requested. It is believed that all claims are now in condition for allowance.

An early and favorable action is earnestly solicited.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
Patents, Trademarks and Copyrights
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940